UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Edith Massiah, on behalf of herself and all others similarly situated, Plaintiff, v. SANOFI-AVENTIS U.S. LLC, SANOFI U.S. SERVICES, INC., and CHATTEM, INC. Defendants.	Civil Action No. 19-11944 **CLASS ACTION COMPLAINT**

Plaintiff Edith Massiah ("Plaintiff"), by her attorneys, makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to allegations specifically pertaining to herself and her counsel, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a prospective class action on behalf of Plaintiff Edith Massiah ("Plaintiff") and all others similarly situated against Defendants Sanofi-Aventis U.S. LLC, Sanofi U.S. Services, Inc. (collectively "Sanofi"), Chattem, Inc. ("Chattem") (collectively with Sanofi, "Defendants").

2. This action concerns Defendants' manufacturing and distribution of ranitidine-based over-the-counter medications under the brand name Zantac that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a liver-damaging impurity that the World Health Organization has described as "clearly carcinogenic" and the U.S. Environmental Protection Agency has referred to as a "potent carcinogen."

3. Defendants manufactured or distributed Zantac in New York and throughout the

United States.

4. Zantac belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach.

5. Zantac is used to treat gastrointestinal conditions including heartburn, sour stomach, acid indigestion and gastroesophageal reflux disease, commonly known as GERD.

6. Defendant Sanofi's manufacturing process has caused Zantac to contain dangerously high levels of NDMA.

7. A 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."

8. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine medications, including Zantac. The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."

9. The FDA has advised companies to recall their ranitidine products if their testing shows levels of NDMA above the acceptable daily limit of (96 nanograms per day or .32 parts per million). Testing by Valisure, an FDA-registered online pharmacy found that Zantac samples contained NDMA content of between 2.5-3.3 million nanograms per tablet.

10. Moreover, the Medicines and Healthcare Regulatory Agency of the United Kingdom has issued an alert regarding Zantac, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA." The Agency has asked manufacturers to quarantine

all ranitidine products which may contain NDMA.

11. Similarly, governmental regulatory authorities in Germany, Austria, Switzerland, Ireland and other nations have issued a recall of ranitidine-based drugs, including Zantac.

12. In addition, several pharmaceutical manufacturers have issued voluntary recalls or halted the sale of their ranitidine medications. Pharmacies such as CVS and Walgreens have also pulled Zantac from its shelves. Both companies have offered refunds to its customers who purchased Zantac from its stores.

13. Both before and after the FDA's announcement, Defendants touted the safety of its products on Zantac's website.

14. For example, Sanofi informs consumers that it is safe to "take up to two (2) Zantac tablets a day."

15. Furthermore, in response to outcry concerning NDMA contamination, Defendants issued a statement on Zantac's website stating: "The longstanding science supports the safety of Zantac, which has been available over-the-counter for over two decades."

16. Despite Defendants' continued claims that Zantac is safe, the product contains dangerously high levels of NDMA that would not be present if the medication were properly synthesized.

17. Plaintiff and the Class were injured by the full purchase price of their Zantac products. These products are worthless, as they contain harmful levels of NDMA. The medications are not fit for human consumption because they expose users to NDMA levels well above the legal limit.

18. In addition to full refunds, Plaintiff and the Class members are further entitled to statutory damages, damages for the injury sustained in consuming high levels of toxic NDMA,

and for damages related to Defendants' conduct.

19. Plaintiff also seeks equitable relief and to recover damages and restitution for the following claims: (a) unjust enrichment, (b) fraudulent concealment, (c) express warranty, (d) implied warranty of merchantability, (e) violation of New York General Business Law § 349, and (f) violation of New York General Business Law § 350.

PARTIES

20. Plaintiff Edith Massiah is resident of Bronx, County, New York. During the Class Period, she paid money for one or more Zantac over the counter products in New York manufactured by Defendant Sanofi, distributed by Defendant Chattem.

21. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi, S.A. Sanofi Aventis, U.S. has been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the State of New York.

22. Defendant Sanofi U.S. Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi, S.A.

23. Defendant Chattem, Inc. is a corporation incorporated under the laws of Tennessee with its principal place of business at 1715 West 38th Street, Chattanooga, Tennessee 37409. Chattem manages the supply and distribution of Zantac in the United States on behalf of Sanofi.

24. Defendant Chattem, Inc. is a corporation incorporated under the laws of Tennessee with its principal place of business at 1715 West 38th Street, Chattanooga, Tennessee

37409. Chattem manages the supply and distribution of Zantac in the United States on behalf of Sanofi.

25. There exists a unity of ownership between Sanofi, Chattem, and their agents such that any individuality or separateness between them has ceased and each of them is the alter ego of the other. Upon information and belief, Sanofi communicates with Chattem concerning virtually all aspects of the Zantac it distributes in the United States. At all relevant times, Chattem acted as an authorized agent, representative, servant, employee and/or alter ego of Sanofi while performing activities including but not limited to advertising, warranties, dissemination of information, and distribution of Zantac medications in the United States and in the State of New York.

JURISDICTION AND VENUE

26. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

27. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendants (i) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of defective Zantac in this District; (ii) conduct substantial business in this District; and (iii) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

28. Plaintiff seeks to represent a class defined as all persons in the United States who purchased Zantac (the "Class").

29. Plaintiff also seeks to represent a subclass defined as all members of the Class who purchased Zantac in New York ("the New York Subclass").

30. Excluded from the Classes are the Defendants, the officers and directors of the Defendants at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which any Defendant has or had a controlling interest.

31. Also excluded from the Classes are persons or entities that purchased Optic White for purposes of resale.

32. Plaintiff is a member of the Classes she seeks to represent.

33. The Classes are so numerous that joinder of all members is impractical. Although Plaintiff does not yet know the exact size of the Classes, Zantac has been sold in major retail stores across the United States, including stores such as CVS, Target and Walgreens and major online retailers include Amazon.com and Drugstore.com. Upon information and belief, the Class includes more than one million members.

34. The Classes are ascertainable because the Class Members can be identified by objective criteria – the purchase of Zantac during the Class Period. Individual notice can be provided to Class Members "who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B).

35. There are numerous questions of law and fact common to the Class which predominate over any individual actions or issues, including but not limited to:

a. Whether Defendants fraudulently concealed that Zantac was contaminated and unsafe;

b. Whether Defendants' marketing of Zantac is an unfair business practice;

c. Whether Defendants breached an express warranty made to Plaintiff and the Class;

d. Whether Defendants violated the General Obligations Law in marketing Zantac as safe;

e. Whether Class Members suffered an ascertainable loss as a result of Defendants' conduct as alleged in this Complaint; and

f. Whether, as a result of Defendants' misconduct as alleged herein, Plaintiff and the Class Members are entitled to restitution, injunctive and/or monetary relief and, if so, the amount and nature of such relief.

36. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct. Plaintiff has no interests antagonistic to the interests of the other members of the Class. Plaintiff and all members of the Class have sustained economic injury arising out of Defendants' violations of common and statutory law as alleged herein.

37. Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class Members she seeks to represent, she has retained counsel competent and experienced in prosecuting class actions, and she intends to prosecute this action vigorously. The interests of the Class Members will be fairly and adequately protected by Plaintiff and her counsel.

38. The class mechanism is superior to other available means for the fair and efficient

adjudication of the claims of Plaintiff and the Class Members. Each individual Class Member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendants' liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims are consistently adjudicated.

PLAINTIFF'S EXPERIENCE

39. Ms. Massiah purchased and consumed Zantac manufactured by Defendant Sanofi and distributed by Defendant Chattem in approximately September 2019 and at other times prior to that. She typically purchased the product from local convenience stores.

40. If Ms. Massiah had known that taking Zantac would expose her to unsafe quantities of NDMA, she would not have purchased or used the drug.

41. When purchasing Zantac from Defendants, Plaintiff reviewed and relied upon the accompanying labels and disclosures and understood them as representations and warranties by the manufacturer and distributor that the medications were properly manufactured, free from defects, and safe for their intended use. Plaintiff also understood that in making the sales, the direct sellers were acting with the knowledge and approval of Sanofi and/or as the agents of Sanofi.

FIRST CAUSE OF ACTION
Unjust Enrichment

42. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

43. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

44. Plaintiff and the Class and New York Subclass conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective Zantac.

45. Defendants voluntarily accepted and retained this benefit.

46. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

SECOND CAUSE OF ACTION
Fraudulent Concealment

47. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

48. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

49. Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of NDMA.

50. Defendants affirmatively misrepresented to Plaintiff and class members in advertising and other forms of communication, including on the Zantac product packaging, that Zantac had no significant defects and was safe for human consumption.

51. Defendants possessed knowledge of these material facts. They were aware of

dangers of NDMA contamination. Moreover, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels more than 400 times greater than what the FDA considers acceptable." During that time, Plaintiff and Class and New York Subclass members were using Zantac without knowing it contained dangerous levels of NDMA.

52. Defendants had a duty to disclose material facts to Plaintiff and the Class and New York Subclass given their relationship as contracting parties and intended users of Zantac. Defendants also had a duty to disclose material facts to Plaintiff and the Class and New York Subclass, namely that they were in fact manufacturing, distributing, and selling harmful Zantac unfit for human consumption.

53. Defendants failed to discharge their duty to disclose these material facts.

54. Plaintiff and the Class and New York Subclass reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective Zantac manufactured, distributed, and sold by Defendants had they known it contained unsafe levels of NDMA.

55. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class and New York Subclass suffered damages in the amount of monies paid for the defective Zantac.

56. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

THIRD CAUSE OF ACTION
Express Warranty

57. Plaintiff repeats the allegations contained in the paragraphs above as if fully set forth herein.

58. Plaintiff brings this Count individually and on behalf of the members of the prospective Class and the New York Subclass.

59. In connection with the sale of the Products, Defendants issued express warranties to Plaintiff and members of the Class and New York Subclass in its labeling and marketing and advertising, including the warranties that Zantac was safe for use and would include only the products listed on the label and not contain unsafe chemicals such as NDMA.

60. Defendants affirmations of fact and promises made to Plaintiff and the Class and New York Subclass became part of the basis of the bargain between Defendants on the one hand and Plaintiff and members of the Class and New York Subclass on the other hand, thereby creating express warranties that the Products would conform to Defendants' affirmations of fact, representations, promises and descriptions.

61. In making her purchase, Plaintiff relief on the express warranty that the product was safe for use and that the product would not contain dangerous levels of NDMA.

62. Plaintiff and the members of the class were injured as a direct and proximate result of Defendants' breaches of their warranties because: (a) in contrast Defendants' warranties, Zantac is not safe for human consumption and (b) Plaintiffs and members of the class would not have purchased Zantac if they had known the true facts.

63. Defendants breached their express warranties because Zantac is unsafe and contains ingredients not listed on the product label including dangerous levels of NDMA.

64. Plaintiff relied on the express warranty that her Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

65. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on

the label, and not harmful impurities such as NDMA.

66. Plaintiff and the Class and New York Subclass performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medication.

67. Defendants breached express warranties about the defective Zantac and its qualities because Defendants' statements about the defective Zantac were false and the defective Zantac does not conform to Defendants' affirmations and promises described above.

68. Plaintiff and each of the members of the Class and New York Subclass would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained elevated levels of NDMA.

69. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class and New York Subclass have been damaged in the amount of the purchase price of Zantac and any consequential damages resulting from the purchases.

70. Prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendants a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom.

FOURTH CAUSE OF ACTION
Implied Warranty of Merchantability

71. Plaintiff repeats the allegations contained in the paragraphs above.

72. Plaintiff brings this Count individually and on behalf of the members of the prospective Class and New York Subclass.

73. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers of Zantac, issued implied warranties that Zantac is recognized as safe for human consumption and does not contain dangerous levels of NDMA.

74. Defendants breached these implied warranties because Zantac could not pass without objection in the trade under the contract description; the Zantac was a fungible good that was not of fair average quality within the description; the product was not adequately labeled as it did not disclose that the product container harmful levels of NDMA, and the Zantac was unfit for its intended and ordinary purpose because the Zantac manufactured, distributed, and sold by Defendants was defective in that it contained elevated levels of NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff, as well as members of the Class and New York Subclass did not receive the merchantable goods.

75. Plaintiff and members of the Class and New York Subclass and New York relied on Defendants' skill and judgment and the implied warranty of merchantability in making their purchases.

76. The Zantac was defective when it left the exclusive control of Defendants.

77. The Zantac was not altered by Plaintiff or Class and New York Subclass members.

78. Defendants knew that the Zantac would be purchased and used without additional testing by Plaintiff and Class and New York Subclass members.

79. The Zantac was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and New York Subclass members did not receive the goods as warranted.

80. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and New York Subclass members have been injured and harmed because they would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and the product is not generally recognized as safe for human consumption; and (b) Zantac does not have the characteristics, ingredients, uses, or benefits as promised by

Defendants.

FIFTH CAUSE OF ACTION
New York General Business Law § 349

81. Plaintiff repeats the allegations contained in the paragraphs above.

82. Plaintiff brings this Count individually and on behalf of the members of the New York Subclass.

83. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

84. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning of New York's General Business Law § 349.

85. Plaintiff and members of the New York Subclass are consumers who purchased products from Defendants for their personal use.

86. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that Zantac would not contain dangerously high levels of NDMA and is generally recognized as safe for human consumption.

87. The foregoing deceptive acts and practices were directed at consumers.

88. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of Zantac to induce consumers to purchase the same.

89. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

90. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid

for and used Defendants' products.

91. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained high levels of NDMA; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

92. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

SIXTH CAUSE OF ACTION
New York General Business Law § 350

93. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

94. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

95. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

96. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

97. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of New York's General Business Law.

98. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

99. Defendants' false, misleading, and deceptive statements and representations of

fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

100. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

101. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

102. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained elevated levels of NDMA and is not safe for human consumption; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

103. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated prays for relief as follows:

A. Certifying this action as nationwide class action, and certifying a New York Subclass, naming Plaintiff as a representative of the certified class and New York Subclass and her attorneys as class counsel for the class and the New York Subclass;

B. Declaring that the Defendants' conduct violates the statutes and causes of action referenced herein;

C. Awarding compensatory and punitive damages in favor of Plaintiff, members of the Class, and the New York Subclass against Defendants for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

D. Awarding injunctive relief against Defendants to prevent continuing their ongoing unfair, unconscionable, and/or deceptive acts and practices;

E. Awarding Plaintiff and members of the class restitution and/or disgorgement and all other forms of equitable monetary relief and prejudgment interest;

F. Awarding Plaintiff and members the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

G. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable in this action.

Dated: December 31, 2019

The Marlborough Law Firm, P.C.

/s/ Christopher Marlborough

Christopher Marlborough
THE MARLBOROUGH LAW FIRM, P.C.
445 Broad Hollow Road, Suite 400
Melville, New York 11757
Telephone: (212) 991-8960
Facsimile: (212) 991-8952
chris@marlboroughlawfirm.com

Attorneys for Plaintiff